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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,384	06/07/2000	Hanspeter Heiniger	6748	8438

25763 7590 04/09/2002

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,384

Applicant(s)

HEINIGER ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the drawings for the apparatus for subcutaneous administration of an injectable product should include a drawing of the apparatus with the needle in the distal position where in the needle protrudes beyond the needle protection sleeve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because on line 3 of the abstract the word "whereinhe" has been used, this word has been interpreted by the examiner to mean "wherein the". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "distal position" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "its distal position" in line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "distal position" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "its distal position" in line 15, and "its distal position" in line 16. There is insufficient antecedent basis for these limitations in the claim.

Claim 14 recites the limitation "its distal position" in line 2, and "its distal position" in line 3. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 9-11 rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S Patent No.5591138 to Vaillancourt et al.

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Vaillancourt discloses a protected needle assembly. This apparatus contains a housing, a container for product, where the container is accommodated by housing, an injection needle connected to container and protruding beyond the housing, a needle protection sleeve, and an indicator, which indicates to a user that a needle protection sleeve is in its distal position. The housing comprises an inner sleeve and an outer sleeve, between which an annular gap.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,591,138 to Vaillancourt et al.

The indicator for Vaillancourt's apparatus actuates the needle and not the needle sleeve. But Vaillancourt's apparatus achieves the same purpose and outcome. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the indicator actuate the needle sleeve instead of the needle, because the applicant has not disclosed that the movement of the needle sleeve provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the indicator moving the needle

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instead of the needle sleeve, because in both cases the caregiver is aware of the position of the needle.

4. Claims 4-8 and 12-14 area rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5591138 to Vaillancourt as applied to claim 1 above, and further in view of U.S. Patent No. 6287283 to Ljunggreen et al

Vaillancourt's indicator is a manual apparatus for the movement of the needle and the indicator positioning of the needle. It would be obvious to modify the manual apparatus and utilize electronic means of defining the position of the needle, because most of the syringes have modified to become digital. One example is Ljunggreen, which discloses an apparatus for the registration of the setting of a medical device. Ljunggreen utilized a digital electronic display as is common and in practice.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to switch form manual to electronic, because as stated by Ljunggreen digital on the electronic display are more legible in relation to small indicators on the adjustment sleeve. Also, misalignment of this scale in relation to the rim of the outer sleeve might occur. This is obviated according to the invention by the great digits on the display. (Col.4, lines 36-42)

Conclusion

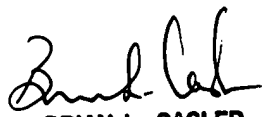
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
March 26, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700